



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,135	03/10/2004	Ralph E. Wood	PC25486B	8812

28523 7590 06/23/2006

PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

HENLEY III, RAYMOND J

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/798,135

Applicant(s)

WOOD, RALPH E.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**CLAIMS 1-7 ARE PRESENTED FOR EXAMINATION**

Applicant's Preliminary Amendment filed March 10, 2004 has been received and entered into the application. Accordingly, the specification at page 1 has been amended.

***Specification Objections***

The disclosure is objected to because of the following informalities:

In the above referenced amendment to the specification, line 2 thereof, ---now abandoned,--- should be inserted after "10/311,907" in order to indicate the current status of the parent application. Also, at the penultimate line of the amendment, "60/215,029", (emphasis added), is incorrect and should be amended to read as ---60/219,029---. Additionally, the misspelled term "cycli" at page 7, line 21 of the specification should be amended to read as ---cyclic---.

Finally, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter, i.e., the expression "a cGMP PDE5 inhibitor or a derivative or salt thereof" does not appear at pages 1-12 of the specification. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the expression "a cGMP PDE5 inhibitor or a derivative or salt thereof", which was set forth in the specification as originally filed, i.e., in claims 1 and 3-6, does not appear at pages 1-12 of the specification. Thus, this expression should be included in the specification, within pages 1-12, as appropriate so that the claimed expression will find proper antecedent basis.

Correction of the above is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*I* Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating diabetic foot ulcers in a patient suffering therefrom, does not reasonably provide enablement for non-limited “treating” of a patient who is suffering from diabetic foot ulcers, i.e., where the therapeutic objective for treating a patient suffering from diabetic foot ulcers is not specified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

***Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph***

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that a patient suffering from diabetic foot ulcers may be “treated” in general and in a non-limited manner is doubted because the claim encompasses the treatment of *any and all* diseases/conditions in the patient who is also suffering from diabetic foot ulcers, and such reads on the claim designated cGMP PDE5 inhibitor or a

Art Unit: 1614

derivative or salt thereof acting as a panacea, while such is not recognized in the pharmaceutical/medical art.

In particular, the art is currently unaware of any compound, or combination of compounds, that may be effectively used to treat any and all diseases in a host and lacking such knowledge, the skilled artisan would be faced with the impermissible burden of undue experimentation in attempting to practice the present invention in a manner commensurate in scope with present claim 4.

While, for factual support of the above position, the Examiner cannot locate a reference containing an express teaching that a panacea does not exist, the following references are offered in support of the Examiner's position: Kumar (cited by the Examiner, reference "V" on the attached form PTO-892) teaches "The role of melatonin in organisms physiology has now been widely recognized, and the wealth of information accumulated in the past two decades indicate it to be the best hormone candidate to be investigated for a universal panacea." (penultimate and last line of the abstract); Oka et al. (cited by the Examiner, reference "W" on the attached form PTO-892) teaches "At the present time, however, there is no single panacea. To achieve the maximum preventive and therapeutic effects with the minimum toxicity, two or more immunosuppressive drugs are used appropriately in combination, taking the mechanisms of action of each into consideration (penultimate and last line of the abstract); Smith et al. (cited by the Examiner, reference "X" on the attached form PTO-892) teaches "[hormone replacement therapy] is not a panacea for an unhealthy lifestyle." (line 11 of the abstract); and Rickels et al. (cited by the Examiner, reference "U" on the attached form PTO-892) teaches "Anxiolytics are

Art Unit: 1614

not a panacea, but only tools to allow the patient to help himself or herself.” (lines 11-12 of the abstract).

Thus, for the above reasons, claim 4 is deemed properly rejected.

Applicant may wish to consider amending claim 4 to read “A method of treating a diabetic foot ulcer in a patient suffering therefrom comprising administering an effective amount...”, (or similar verbiage) in order to overcome the present rejection.

**II** Claim 5 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating diabetic foot ulcers or else inhibiting the formation thereof, does not reasonably provide enablement for preventing the formation of foot ulcers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

#### ***Overcoming this Point of Rejection***

In order to overcome this point of rejection, Applicant may wish to consider amending claim 5 to read “A method of inhibiting the formation of foot ulcers...”. While such does not express support in the specification as originally filed, the concept of inhibiting the formation of foot ulcers would be immediately envisaged by the skilled artisan upon reading the specification as a whole.

#### ***Ground of Rejection***

The burden of enabling the prevention of any disease or condition, such as the claimed foot ulcers in a diabetic patient, would be much greater than that of enabling the treatment of such diseases/conditions. In the instant case, the specification does not provide sound, acceptable guidance as to how one skilled in the art would accomplish the objective of preventing foot

Art Unit: 1614

ulcers, except for the mere statement that such may be accomplished through the administration of a cGMP PDE5 inhibitor or a derivative or salt thereof. Also, the present specification lacks sufficient guidance as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing a foot ulcer in a diabetic patient.

It is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified actives could actually prevent a foot ulcer in a diabetic patient by simply administering, by any method, an effective amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the method of the present claim for preventing foot ulcers where in practicing such method steps as are set forth, the artisan would be imbued with a reasonable expectation that prevention of the foot ulcers would be successful.

The term “preventing”, under the “broad and reasonable interpretation” standard as set forth under MPEP § 2111, is synonymous with the term “curing”, and both circumscribe methods where absolute success is required. Because absolute success is not reasonably possible or expected in the treatment of most diseases/disorders, the present specification is viewed as lacking an adequate enabling disclosure of the same where the only enablement offered for such prevention is the mere statement that such prevention may be accomplished if one were to simply administer the claim designated actives in the manner as prescribed in the present claim.

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use

Art Unit: 1614

will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that a foot ulcer in a diabetic patient could actually be prevented is based, in part, on the teachings of Mason et al., (the Diabetic Medicine article cited by the Examiner). The concept that the artisan would take from reading the Mason et al. article, which is a well written review article that takes into account a significant number of previously written articles in the field of diabetic foot ulcers, (see Tables 1-4 at pages 803-805 and 808), is that foot ulcer prevention in diabetic patients, while being developed in the sense of treating such ulcers once they have formed or inhibiting the formation of such ulcers in a patient who has been identified as at risk therefor, is not developed to the point where prevention, i.e., as established by the absolute non-occurrence of the ulcers in a patient at risk thereof, can be predicted or expected with a reasonable degree of certainty.

Indeed, Mason et al. teaches that “where people with diabetes receive well-organized and regular care with rapid referral to appropriate specialist multidisciplinary teams when problems (or their precursors) occur, ulcer morbidity can be *substantially reduced*”, (emphasis added, see the abstract at page 801 under the heading “Results”). Thus, Mason et al. discloses that even with “well-organized and regular care with rapid referral to appropriate specialist multidisciplinary teams when problems (or their precursors) occur”, only a substantial reduction of foot ulcers may be expected. Clearly, a substantial reduction of foot ulcers, while laudable, does not rise to the level of absolute prevention which is encompassed by the present claim. Given such information, the artisan would require more than Applicant’s mere statement that

Art Unit: 1614

foot ulcers can be prevented with a cGMP PDE5 inhibitor or a derivative or salt thereof, (e.g., see the present specification at page 5, lines 19-22 and present claim 5).

Also, factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the appropriate factors from those above are applied to the present disclosure, (see *infra*), it is the Examiner's position that the present specification would only enable the skilled artisan to treat or inhibit the formation of a foot ulcer in a diabetic patient.

The following is the Examiner's consideration of the relevant factors as discussed above.

(1) The nature of the invention/state of the prior art, relative skill of those in the art, the predictability in the art.

The claim is directed to a method for preventing the formation of foot ulcers in a diabetic patient. The relative skill of those in the art is high.

(2) The breadth of the claims

The claims are not limited to diabetic foot ulcers expressly, but such are encompassed by the present claim because the foot ulcers are indicated to appear in a diabetic patient.

(3) The amount of direction or guidance presented and presence or absence of working examples.

The specification merely provides statements that foot ulcers in diabetic patients may be

Art Unit: 1614

prevented. Experimental data that shows, in fact, the prevention of a foot ulcer in a diabetic patient is not present. The present specification at page 8 provides an anecdotal report of a patient suffering from erectile dysfunction as well as foot ulcer where it was observed that in the course of treatment for erectile dysfunction with sildenafil, i.e., a cGMP PDE5 inhibitor, the ulcer tended to heal, despite having a history of not healing very well. The Example does not, however, show that patient at risk of developing a foot ulcer, (e.g., a diabetic patient suffering from peripheral neuropathy), when administered a cGMP-PDE5 inhibitor, actually did not develop a foot ulcer, (of course such would need to be established through a well designed, controlled and blinded clinical trial). cholesterol-associated tumor. It should be understood that the present rejection is not founded, either wholly or in-part, on the observation that the present specification lacks a working example. Indeed, a working example is not required in order to satisfy the enablement requirement under 35 U.S.C. § 112, first paragraph, (e.g., see MPEP § 2164.02). However, when all relevant factors are considered and weighed, the lack of a working example tends to support rather than diminish the Examiner's position.

(4) The quantity of experimentation necessary.

Applicant has failed to provide guidance and information sufficient to allow the skilled artisan to ascertain how to absolutely cure, i.e., prevent, foot ulcers in diabetic patients. Testing would be necessary in the appropriate patient population for all types of foot ulcers with the artisan having no expectation that such ulcers could be successfully prevented as presently claimed.

(5) The State of the Art

As discussed above respecting the Mason et al. reference cited by the Examiner, the state

Art Unit: 1614

of the art is that even with diabetic patients receiving well-organized and regular care with rapid referral to appropriate specialist multidisciplinary teams when problems, (or their precursors), occur, ulcers nevertheless became manifest, albeit reduced in a substantial manner. Substantially reduced, however, does not equate to prevented as the latter is an absolute end-point that is simply not achieved in the art.

### *Summary*

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that prevention of foot ulcers in a diabetic patient could be achieved. In order to actually achieve such prevention, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicant has failed to demonstrate, that foot ulcers in diabetic patients can be prevented, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Also, even in practicing the method steps as defined in the present claim, the artisan would not have the requisite expectation of success but rather would have viewed the claimed outcome as significantly unpredictable given the state of the art as discussed above

Accordingly, for the above reasons claim 5 is deemed properly rejected.

### *Claim Rejections - 35 USC § 112, Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1614

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*I* Claims 1-3 are considered indefinite because they fail to recite a host and thus are incomplete. Also, in claim 4, the term “treating” does not describe any particular means of accomplishing the stated objective of “treating a patient suffering from diabetic foot ulcers”. This is because the term “treat” is used in both the objective and the step to be performed, while not ever actually setting forth the metes and bounds of the term “treat”. Accordingly, the metes and bounds of the subject matter for which applicant seeks patent protection is unclear.

In order to overcome the above points of rejection, the claims should be amended to include a host, (i.e., claims 1-3), or to specify how the treatment objective is accomplished, (i.e., by including a step of administration in claim 4).

*II* “The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.” (MPEP 2173).

Respecting all claims, (i.e., claims 1-7), the term “derivative” in the expression “a cGMP PDE5 inhibitor or a derivative or a salt thereof”, (see claims 1 and 3-6), is a relative term which renders the claim indefinite. In particular, “derivative” does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and

Art Unit: 1614

still be considered a “derivative” as intended by Applicant. Applicant has failed to provide any specific definition for this term in the present specification. Lacking a clear meaning of the term “derivative” as intended by Applicant, the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection. At best, only by subjective interpretation of the term “derivative” could one skilled in the art begin to guess at which compounds are intended to be excluded or included by Applicant. Such is not, however, consistent with the tenor and express requirements of 35 U.S.C. § 112, second paragraph.

***Suggestion for Overcoming this Point of Rejection***

Because the specification as originally filed is inadequately detailed with respect to chemically-specific types of derivatives, except for salt forms of cGMP PDE5 inhibitors, the present claims should be amended to delete the expression “a derivative” in order to overcome the above point of rejection.

Alternatively, for those references which have been properly incorporated by reference, (e.g., U.S. patent or non-patent literature documents which themselves do not incorporate essential subject matter therein), and which contain the concept of derivatives of cGMP PDE5 inhibitors in general, specifically disclosed derivatives may be expressly added to the present specification and claims. Applicant is advised to carefully consider MPEP §608.01(p)(I) and/or 37 C.F.R. § 1.57 if electing to choose this option for overcoming the present rejection, especially with respect to the identification of those references which may be properly incorporated by

Art Unit: 1614

reference into a U.S. Patent application, as well as the subject matter intended for insertion in the present application which is actually and specifically disclosed in such references

Accordingly, the claims are deemed properly rejected.

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Bombrun (U.S. Patent No. 6,043,252, cited by the Examiner).

Bombrun teaches that various cGMP PDE5 inhibitors (col. 1, lines 11-19) may be used for the treatment of peripheral vascular diseases, including Raynaud's disease, i.e., Raynaud's phenomenon, (see col. 14, lines 12 and 13). The patentee further teaches the manufacture of a medicament comprising a cGMP PDE5 inhibitor which comprises admixing the cGMP PDE5 inhibitor with a carrier material so as to form a pharmaceutical composition useful in the disclosed method of treatment, (see col. 14, line 64 – col. 15, line 18).

The language present in claim 6, i.e., "a diabetic foot ulcer therapeutic", represents a statement of intended use and does not impart any physical or otherwise material feature to the presently claimed composition produced by the method of claim 6 or to the method of manufacture defined by present claim 6 that is not found in either the composition or method of

Art Unit: 1614

its manufacture as disclosed by Bombrun. Accordingly, such language does not represent a patentable distinction.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombrun, for the reasons set forth above, which reasons are here incorporated by reference, in view of Graham (U.S. Patent No. 6,075,028, cited by the Examiner).

The difference between the above and the claimed subject matter lies in that Bombrun fails to teach (i) that the patient being treated suffers from diabetic foot ulcers or (ii) sildenafil as being useful as the cGMP PDE5 inhibitor.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the subject matter of present claim 4 does not define the treatment of a specific disorder, but rather only to the treatment broadly of a patient who suffers from diabetic foot ulcers. It is not seen in Bombrun that any teaching would preclude the treatment of any of the disorders listed at col. 14, lines 5-19 in a patient who also may suffer from other diseases and/or conditions, such as diabetic foot ulcers.

Art Unit: 1614

Also, with respect to present claim 7, Graham teaches sildenafil as being a cGMP PDE5 inhibitor (col. 2, lines 17-25) and thus would have motivated the skilled artisan to use sildenafil in the manner taught by Bombrun for drugs which are cGMP PDE5 inhibitors. That is, because Bombrun teaches that cGMP PDE5 inhibitors in general may be employed, this knowledge would have imbued the skilled artisan with at least a reasonable expectation that sildenafil could be used in the manner taught by Bombrun for cGMP PDE5 inhibitors because, as established by Graham, the artisan would have recognized sildenafil as belonging to the cGMP PDE5 therapeutic class of agents.

Applicant may wish to consider amending claim 4 in a manner similar to claim 5 in order to overcome the present rejection, i.e., by having the language "A method of treating diabetic foot ulcers in a patient suffering therefrom comprising...". Such would overcome the present presumption of obviousness because neither Bombrun nor Graham teaches or suggests that a cGMP PDE5 inhibitor, such as sildenafil, would be effective for the treatment of diabetic foot ulcers in a patient suffering therefrom.

***Allowable Subject Matter***

Aside from the issue raised above under 35 U.S.C. § 112, second paragraph, respecting the term "derivative" as well as the absence of host to whom the active agent is administered, present claim 3 is deemed in condition for allowance. Claim 3 is allowable over the references of record because none of such references teach or suggest that a cGMP PDE5 inhibitor, such as sildenafil, would be useful in a method for treating onychomycosis, (i.e., a fungal infection of the nailbed), which comprises the administration of such an inhibitor to a patient suffering therefrom.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

June 20, 2006